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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,349	09/30/2003	Michael L. Bell	2083-045/13872	8034

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EXAMINER

NAGPAUL, JYOTI

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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12/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/676,349

Applicant(s)

BELL, MICHAEL L.

Examiner

Jyoti Nagpaul

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment filed on October 12, 2007 has been acknowledged. Claims 1-23 are pending.

Response to Amendment

Rejection of Claims 1-23 as being unpatentable over Mitsumaki (US 4680270) in view of Ricchio (US 5130095) has been modified in light of applicant's amendments.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claims 1-23** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's recite "wherein the base unit and the analysis unit are capable of being alternatively disposed in: a disconnected configuration wherein the analysis unit is separate from the base unit; and a connected configuration wherein the reagent outlet is connected to the reagent inlet". The limitation "capable of" is intended use and is of no patentable significance in apparatus claims. If applicant's intend to limit the structure, it is suggested that applicant's not use "capable of". Additionally, applicant's recite "alternatively". It is unclear from the claim language as to what is alternatively disposed. Clarification is needed.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. **Claims 1-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitsumaki (US 4680270) in view of Ricchio (US 5130095).

Mitsumaki teaches a method and apparatus for conducting flow analysis. The system comprises a portable analysis unit comprising:

a sample inlet (1)

an analyzer (12) for determining a characteristic of a sample and providing data about the characteristic

a reagent supply reservoir (10)

a collection reservoir (130)

a supply conduit (93) from the reagent supply reservoir (10) to the analyzer (12)

a waste conduit (110) from the analyzer (12) to the collection reservoir (130)

a power source/microprocessor-equipped control unit is inherent in the teachings of Mitsumaki for providing power to the analyzer (12)

a data output element/printer for outputting data generated by the analyzer (12)

a pressure source (11 and 15, respectively) for moving reagent and waste

With respect to Claim 2, a multiport valve (90 or 100) coupled to the pressure source (11), the supply conduit (93), and the waste conduit (110)

With respect to Claim 3, a reaction chamber (20b) coupled to the multiport valve (90 or 100)

With respect to Claim 4, the analysis unit further comprises a wash fluid supply reservoir (9) coupled to the multiport valve (90 or 100).

With respect to Claim 5, the analysis unit further comprises a support fluid supply reservoir (52) coupled to the multiport valve (90 or 100).

With respect to Claims 6 and 7, the portable analysis unit further comprises a controller/microcomputer (21) for controlling the analyzer and the multiport valve. The microcomputer is capable of inputting data and outputting data.

With respect to Claim 8, the analysis unit further comprises a user input device (26) for inputting data into the analysis unit microcomputer.

With respect to Claims 9-11, Mitsumaki teaches an automated system for calibrating and cleaning the system. It is inherent that the controller/microcomputer contains a set of instructions for directing the automatic self-calibrating and self-cleaning of the analysis unit.

With respect to Claim 17, the portable analysis unit further comprises a control sample inlet/inlet into the valve (6). Ricchio further teaches a control sample storage reservoir (7) and a control sample outlet/the end of the conduit in the container (7) with the control sample as shown in Figure 1 for providing control sample from the control sample storage reservoir (7) to the control sample inlet/inlet located in the valve (6).

With respect to Claim 18, the analyzer is a cytometer flow cell (120).

With respect to Claim 20, the pressure source is a pump (11 or 15).

With respect to Claim 21, the method comprises selecting the portable analysis unit, obtaining a sample, entering the sample into the sample inlet (1) and analyzing the sample to obtain an analysis for the sample. (See Columns 3 and 4) Examiner notes, fact that a claimed device is portable or movable is not sufficient by itself to patentably distinguish over an otherwise old device unless there are new or unexpected results. (See In re Lindberg)

Mitsumaki fails to teach a reagent inlet of the reagent supply reservoir (10) for providing reagent to the supply reservoir (10). Mitsumaki fails to teach a waste outlet of

the collection reservoir (130) for removing waste from the collection reservoir (130). Mitsumaki fails to teach a base unit adapted for connection to the analyzer unit for providing reagent to the analysis unit and receiving waste from the collection reservoir. Mitsumaki fails to teach the base unit comprises a reagent storage reservoir, a waste storage reservoir and a waste inlet for connection to the waste outlet of the analysis unit. Mitsumaki further fails to teach a reagent outlet for providing reagent from the reagent storage reservoir to the reagent inlet of the analysis unit. Mitsumaki fails to teach a wash fluid inlet for providing wash fluid to the wash fluid supply reservoir (9). Mitsumaki further fails to teach a base unit comprising a wash fluid storage reservoir and a wash fluid outlet for providing wash fluid from the wash fluid storage reservoir to the wash fluid inlet of the analysis unit. Mitsumaki further fails to teach a support fluid inlet for providing support fluid to the support fluid supply reservoir (52) and the base unit further comprising a support fluid storage reservoir and a support fluid outlet for providing support fluid from the support fluid storage reservoir to the support fluid inlet of the analysis unit. Mitsumaki fails to teach a set of instructions for directing the automatic self-replenishing of reagent in the reagent supply reservoir. Mitsumaki further fails to teach a base unit further comprises a pump for providing reagents from the reagent storage reservoir to the portable analysis unit reagent inlet.

Ricchio teaches an automatic chemistry analyzer. The analyzer comprises a portable analysis unit and a base unit (10). The portable analysis unit comprises a reagent inlet (69) of a reagent supply reservoir/cylindrical tube (87) for providing reagent

(53) to the supply reservoir/cylindrical tube (87) and a waste outlet (49) of a collection reservoir/waste basin (34) for removing waste from the collection reservoir/waste basin (34). Ricchio further teaches a base unit (10) adapted for connection to the analyzer unit for providing reagent to the analysis unit and receiving waste from the collection reservoir. Ricchio further teaches the base unit (10) comprises a reagent storage reservoir (59), a waste storage reservoir (51) and a waste inlet (50) for connection to the waste outlet (49) of the analysis unit. Ricchio further teaches a reagent outlet (62) for providing reagent (53) from the reagent storage reservoir (59) to the reagent inlet (69) of the analysis unit. (See Figure 5) Ricchio teaches an automated chemical analyzer. Thus, it is inherent that Ricchio teaches a set of instructions for directing the automatic self-replenishing of reagent in the reagent supply reservoir cylindrical tube (87). Ricchio teaches a pump (17) for providing reagents from the reagent storage reservoir (59) to the portable analysis unit reagent inlet (69). Ricchio further teaches the base unit (10) further comprises a controller/microprocessor control coupled to the base unit pump (17). Ricchio further teaches the base unit (10) further comprises a user input/keyboard (102) for inputting data into the base unit controller.

It would have been obvious to a person of ordinary skill in the art to modify the device of Mitsumaki to provide a base unit adapted for connection to the analyzer unit for providing reagent to the analysis unit and receiving waste from the collection reservoir in order to easily access the reagent storage reservoir when replenishing the

reagent solution and easily access the waste storage reservoir when discarding the waste and thus increasing the overall process as disclosed in Ricchio.

With respect to "wherein the base unit and the analysis unit are capable of being alternatively disposed in: wherein the base unit and the analysis unit are capable of being alternatively disposed in: a disconnected configuration wherein the analysis unit is separate from the base unit; and a connected configuration wherein the reagent outlet is connected to the reagent inlet and the waste inlet is connected to the waste outlet and wherein the analysis unit is capable of analyzing a sample while in the disconnected configuration". It is inherent that the analysis unit of Mitsumaki is capable of analyzing a sample.

It would have been obvious to a person of ordinary skill in the art to modify the device of Mitsumaki to provide a base unit including a reagent storage reservoir with a reagent outlet for connection to the reagent inlet of the analysis unit in order to replenish the reagent supply reservoir during operation of the device and thus increasing the efficiency of the process as disclosed in Ricchio.

It would have been obvious to a person of ordinary skill in the art to modify the device of Mitsumaki to provide a base unit including a waste storage reservoir with a waste inlet for connection to the waste outlet of the analysis unit in order to empty or

discard the waste in the collection reservoir of the analysis unit and thus increasing the efficiency of the process as disclosed in Ricchio.

It would have been obvious to a person of ordinary skill in the art to modify the device of Mitsumaki to provide a base unit including a wash fluid storage reservoir and a wash fluid outlet for providing wash fluid from the wash fluid storage reservoir to a wash fluid inlet of the analysis in order to replenish the a wash fluid supply reservoir during operation of the device and thus increasing the efficiency of the overall process as disclosed in Ricchio for the reagent supply reservoir.

It would have been obvious to a person of ordinary skill in the art to modify the device of Mitsumaki to provide a base unit including a support fluid supply reservoir and a support fluid outlet for providing support fluid from the support fluid supply reservoir to a support fluid inlet of the analysis unit in order to replenish the a support fluid supply reservoir during the operation of the device and thus increasing the efficiency of the overall process as disclosed in Ricchio for the teachings of the reagent supply reservoir.

It would have been obvious to a person of ordinary skill in the art to modify the device of Mitsumaki to provide a base unit comprising a pump for providing reagents from the reagent storage reservoir to the portable analysis unit reagent inlet and a controller coupled to the base unit pump in order to more efficiently obtain the relative rations of fluids to be pumped into the system as disclosed in Ricchio.

Response to Arguments

7. Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of a modified rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Nagpaul whose telephone number is 571-272-1273. The examiner can normally be reached on Monday thru Friday (8:00-4:30).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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JN


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